EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

MenQuadfi

Date: March 2024

Unit: Technical Assessment Unit

Assessment report

MenQuadfi

Administrative information:

Invented name of the medicinal product:	MenQuadfi
INN (or common name) of the active substance(s):	Meningococcal group A, C, W135, Y conjugated to Tetanus Toxoid
Manufacturer of the finished product	Sanofi Pasteur Inc., 1 Discovery Drive, Swiftwater, PA 18370 - USA
Marketing Authorization holder	Sanofi Pasteur Inc., 1 Discovery Drive, Swiftwater, PA 18370 - USA
Applied Indication(s):	Active immunization of individuals from the age of 2 years and older against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y
Pharmaceutical form(s) and strength(s):	Solution for injection, clear colourless solution. Strength: 10 mcg
Route of administration	For intramuscular injection only, preferably in the deltoid region or anterolateral thigh depending on the recipient's age and muscle mass.
Approved pack	Carton box containing one or 10 single dose vials of 0.5 ml, clear type 1 glass with chlorobutyl stopper, aluminum flip-off seal fitted with plastic cap and insert leaflet

List of abbreviations

AS	Active substance
FP	Finished product
CTD	Common technical document
EMA	European Medicines Agency
GMP	Good manufacturing practice

Dossier initial submission and evaluation process.

- The product was submitted for registration according to ministerial decree No. 343/ 2021 through normal track pathway.
- The dossier was initially received by the registration administration units on 24.11.2022 after providing all the required documents (Full CTD for the product).

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1. **General introduction about the product including brief description of the AI, its mode of action and indications**

- The finished product (FP) is presented as a 0.5 mL solution for injection containing as active substance (AS) 10 µg each of four serogroups A, C, W (also referred to as W135) and Y meningococcal polysaccharide (PS), individually conjugated to 55 µg tetanus toxoid carrier.
- Other ingredients are: sodium chloride, sodium acetate and water for injection. The conjugate vaccine FP is available in a 2 mL Type I borosilicate clear glass vial with a chlorobutyl stopper. the filled vial with stopper is sealed with aluminum seal with plastic flip cap.
- The FP is a unit dose liquid presentation for intramuscular use.
- MenQuadfi is indicated for active immunization of individuals from the age of 2 years and older, against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y.
- Vaccination with MenQuadfi leads to the production of bactericidal antibodies directed against the capsular polysaccharides of serogroups A, C, Y, and W. Bactericidal anti-capsular antibodies have been associated with protection from invasive meningococcal disease due to serogroups A, C, W, and y.

2. **Quality aspects:**

- **Manufacturer(s)**

For the active substance:

Sanofi Pasteur Inc., 1 Discovery Drive, Swiftwater, PA 18370 - USA is responsible for manufacture of the AS intermediate (N. meningitidis polysaccharide purified bulk powder) and AS (N. meningitidis polysaccharide tetanus toxoid conjugate concentrate, serogroup A, C, Y, and W).

Sanofi Pasteur, 1541, Avenue Marcel Mérieux, 69280 Marcy l'Etoile - France is responsible for manufacture of the tetanus toxoid carrier protein (concentrated tetanus protein intermediate).

For the finished product:

The manufacture and control of Meningococcal polysaccharide (serogroups A, C, Y, and W135) tetanus toxoid conjugate vaccine take place in Sanofi Pasteur Inc., 1 Discovery Drive, Swiftwater, PA 18370 - USA

- **Stability**

Drug substance:

Approved Shelf Life:

vaccine bulk: 6 Months

active substance: 48 Months

Approved storage conditions:

vaccine bulk: 1°C – 5°C

active substance: -80ºC to -60°C

Drug product:

Approved storage conditions for drug product:

Store in refrigerator (2°C – 8°C). Do not freeze.

Approved Shelf Life:

48 Months

- **Adventitious agents**

- A list of materials of animal origin used for establishment of the meningococcal seed lot system were provided.

-For the master seed, no material of biological origin was used. Raw materials of ruminant origin are used in the production of Clostridium tetani seed lots (skimmed milk, meat extract, casein peptone, L-cysteine) and concentrated purified tetanus protein bulk (casein peptone, tryptone V, beef heart infusion, l-tyrosine, peptide N3).

-The seed lots are tested for purity and the manufacturing process is performed aseptically and includes bacterial inactivation during the purification of the bacterial antigens. The finished product is tested for sterility. Viral clearance studies for the bacterial vaccine are not required as there is no host available for the propagation of virus. Therefore, there is a low risk for contamination with adventitious agents, which is acceptable.

3. Non-clinical and clinical aspects:

-MenACYW conjugate vaccine was shown to be immunogenic and safe as observed in the immunogenicity study and in the nonclinical safety package showing that repeated administrations of the vaccine were well tolerated.

- In conclusion the overall benefit/risk of Menquadfi is favorable in active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W-135 and Y for use in individuals 2 years of age and older.

General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/assessment-report/menquadfi-epar-public-assessment-report_en.pdf